5/18/99

OVERVIEW OF AZINPHOS-METHYL REVISED RISK ASSESSMENT

Introduction

This document summarizes EPA's human health risk findings and conclusions for the organophosphate pesticide azinphos-methyl, as presented fully in the document, "The Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Azinphos-Methyl (PC Code 058001)", dated May 19, 1999. The purpose of this overview is to assist the reader by identifying the key features and findings of this risk assessment and to better understand the conclusions reached in the assessment. This overview was developed in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy and that it was not easy to compare the assessments for different chemicals due to the use of different formats.

The revised human health risk assessment for azinphos-methyl will be placed in the Pesticide Docket on May 19, 1999, and a 60 day public participation period on risk management will begin.

It has been determined that the organophosphates (OPs) share a common mechanism of toxicity; the inhibition of cholinesterase levels. As required by FQPA, a cumulative assessment will need to be conducted to evaluate the risk from food, water and non-occupational exposure resulting from all uses of OPs. Currently, the Agency is developing the draft methodology needed to conduct such an assessment with guidance/advise provided by the Science Advisory Panel. It is anticipated that this draft methodology will be available for comment and scientific review in the late summer/early fall of 1999. Consequently, the risks summarized in this document are only for azinphos-methyl.

Use Profile

- **Insecticide:** Registered for use on the following crops: Pome Fruits (Apples, Crabapples, Pears & Quinces), Stone Fruits (Peaches, Cherries, Nectarines, Plums & Prunes), Tree Nuts (Almonds, Hazelnuts, Pecans, Pistachios & Walnuts), Fruiting Vegetables (Tomatoes, Eggplants & Peppers), Cucurbits (Cucumbers & Squash), Leafy Vegetables (Celery & Spinach), Brassica Vegetables (Broccoli, Brussels Sprouts, Cabbage & Cauliflower), Vegetables (Snap Beans), Forage Crops (Alfalfa, Birdsfoot Trefoil & Clover), Bulb Vegetables (Onions), Melons (Watermelons, Winter Melons, Cantaloupes & Honeydew), Roots & Tubers (Potatoes), Caneberries (Blackberries, Boysenberries, Blueberries, Raspberries & Loganberries), Citrus Fruits (Oranges, Grapefruits & Lemons), Miscellaneous Crops (Strawberries, Pomegranates, Cranberries, Grapes, Cotton & Sugarcane) and Ornamentals & Trees.

- **Formulations:** Formulated as a liquid emulsifiable concentrate (22% EC); wettable powder (35% & 50% WP), including water soluble bags; and water dispensable granules (50%).

- **Method of Application:** Applied by airblast sprayers, aerial chemigation, groundboom sprayers, low & high pressure hand wands, and fixed-wing & helicopter aircraft.

- **Use Rates:** Maximum use rates (lbs a.i./acre) and the maximum number of applications allowed yearly vary with crop types, as follows (lbs a.i./acre; # of applications): Pome Fruits (0.88-1.5; 4-5), Stone Fruits (0.75-2.0; 4-9), Tree Nuts (2.0-2.5; 3), Fruiting Vegetables (0.44-1.5; 3-4), Cucurbits (0.5; 3), Leafy Vegetables (0.5; 3-4), Brassica Vegetables (0.75; 3-4); Forage Crops (0.5-0.75; 1-2), Bulb Vegetables (0.75; 3), Melons (0.5; 3-4); Root & Tuber Vegetables (0.75; 3), Caneberries (0.5-2; 2-4), Citrus Fruits (2.0-3.0; 2-7); Cotton (1.0; 4); and Ornamental and Trees (4.0-6.0; 6).

- **Annual Poundage**: U.S. estimates for total usage range from approximately 2 million (average use) to 5 million (maximum use) lbs a.i./year. Ten crops account for approximately 93% of the total pounds a.i. applied (in descending order): apples, cotton, almonds, sugarcane, pears, walnuts, cherries (sweet and tart), peaches, pistachios, and tomatoes.

- **Technical Registrants:** Bayer Corporation; Makhteshim Agan; & Gowan Company.

Human Health Risk Assessment

Acute Dietary (Food) Risk

Acute dietary risk is calculated considering what is eaten in one day (in this instance, the individual who consumed the most) and maximum, or high-end residue values in food. A risk estimate that is less than 100% of the acute Reference Dose (aRfD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's risk concern.

- The risk estimates provided below, including all crops in the analysis, which illustrate some of the subpopulations of concern, exceed the level of concern for acute dietary exposure, e.g. for children (age 1-6) at the 99.9th percentile. A limited analysis was conducted which shows that using the 99.9th percentile, the risk is not driven by an individual with an extreme consumption pattern nor by unusual residue levels. A more complete analysis is underway.

- At the 99th percentile of exposure, risk estimates for all subgroups are not a concern.

- Several different dietary scenarios were conducted, that excluded individual crops believed to contribute significantly to risk, in order to ascertain estimates of the relative contribution of these crops to the overall risk estimates. The results demonstrate that apples, peaches and pears are the major contributors to risk estimates.

Table 1 Risk Estimates as a Percentage of the Acute RfD (% aRfD)

Population	Percentile			
	95th[1]	99.9th[2] March 1, 1999	99.9th[2] April 27, 1999	99.9th[2] May 19, 1999
General U.S.	4670%	85%	68%	59%
Infants < 1 yr	10,000%	331%	105%	100%
Children 1-6	10,000%	202%	135%	130%
Children 7-12	NR	129%	98%	90%

[1]Tier 1 non-probabilistic: Risk @ 95th percentile of exposure
[2]Tier 3 probabilistic: Risk @ 99.9th percentile of exposure

- The endpoint is 1.0 mg/kg, the lowest dose tested in the rat acute neurotoxicity study; thus this dose level was considered a LOAEL (Lowest Observed Adverse Effect Level). Therefore, a 3x uncertainty factor was applied due to the lack of a NOAEL (No Observed Adverse Effect Level). The LOAEL was selected based on inhibition of plasma, red blood cell, and brain cholinesterase.

- The FQPA 10x safety factor was removed, because the toxicology data base is complete, developmental and reproductive studies in animals showed no increased susceptibility in fetuses or pups, and there was no evidence of abnormalities in the development of the fetal nervous systems.

- The Uncertainty Factor is 300x; 10x for interspecies extrapolation, 10x for intraspecies variability, and 3x for use of a LOAEL in place of a NOAEL in the critical study.

- The acute dietary RfD is 0.003 mg/kg/day.

- The acute dietary risk assessment has been extensively refined in many cases, using USDA Pesticide Data Program (PDP) data, which reflect actual uses. The most refined analysis conducted for azinphos-methyl included: (1) PDP monitoring data for blended commodities; (2) PDP composite data adjusted for single servings; (3) PDP single serving monitoring data; (4) FDA monitoring data; (5) Field trial data for other commodities; and (6) Percent crop treated data. Monitoring data were used for most commodities. (See Attachment 1 for details on refinements used for specific commodities.)

- Comments received did not significantly change the preliminary risk assessment; however, other refinements discussed above did.

- Additional refinements could include some data currently under development (e.g., registrant conducted or sponsored studies on residue reduction, processing, field studies at lower application rates, etc.). However, these data may not change the risk estimates, since the Agency has already included PDP and FDA monitoring data. Studies on reduction of residues due to cooking may reduce the risk estimates. Additionally, single serving data on apples could reduce or increase the estimated dietary risk.

- The registrant submitted an oral human study which could change the toxicological endpoint and/or uncertainty factor for the acute dietary risk assessment, depending on the study itself as well as pending policy decisions.

Chronic Dietary (Food) Risk

Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic RfD (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's risk concern.

The chronic dietary risk (food) does not exceed the Agency's level of concern for the general U.S. population and all subgroups (i.e. <100% of the chronic RfD is utilized).

- The endpoint is red blood cell cholinesterase inhibition from a one year toxicity study in dogs (NOAEL=0.15 mg/kg/day).

- The Uncertainty Factor is 100; 10x for interspecies extrapolation, and 10x for intraspecies variability. The 10x FQPA safety factor was removed, as in the acute assessment.

- The chronic RfD is 0.0015 mg/kg/day.

- The analysis used percent crop treated data; anticipated residues based on field trials; and FDA monitoring data.

- For the highest exposed subgroup, non-nursing infants (<1 year old), 54% of the RfD is occupied.

- Refinements were not made at this time to the preliminary chronic dietary risk assessment, since the risk estimates do not represent a concern. However, refinements such as using PDP data would be made prior to conducting a cumulative risk assessment.

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to ascertain whether modeled or monitoring levels exceed this level. Modeling is considered to be an unrefined assessment and provides high-end estimates.

- Drinking water concentrations for ground water were estimated using limited ground water monitoring data (for highly leachable soils and substrata) and model estimates from the SCI-GROW model; and for surface water using the PRZM/EXAMS surface water model.

- The only environmental degradate of human toxicological concern is the oxygen analog, which was found at a maximum of about 5% of the total amount of pesticide that was applied in a soil aerobic metabolism study. Currently, it cannot be said with certainty if this degradate would be expected to be found in drinking water.

Acute Exposures

- Acute exposures to azinphos-methyl in drinking water may add to dietary risk. The DWLOCs for acute exposure were calculated to be zero because the acute exposure from food alone exceeded the level of concern. Any exposure to azinphos-methyl in drinking water will only make this exceedance larger.

- The maximum modeled concentration of azinphos-methyl in surface water was 50 ppb, excluding the estimate (88 ppb) resulting from the assumption of 17 possible applications to cotton (reflecting some labels which previously had no restriction on the number of applications to cotton). However, the registrants have agreed to reduce the number of applications for cotton to four per season.

- Limited ground water monitoring data suggest that in areas with karst terrain levels could reach approximately 75 ppb in ground water. These data are from one study which has significant uncertainties associated with it. However, the concentrations reported make it prudent to monitor in these areas to determine if these reports are accurate and to determine the extent of contamination.

Chronic Exposures

- Model estimates of the average concentration of azinphos-methyl in ground and surface water indicate that chronic exposure through drinking water is not a concern. Based on its physical-chemical properties, residues of azinphos-methyl are not expected to persist long enough in either ground or surface water-sourced drinking water to pose a chronic exposure scenario of concern. However, additional monitoring data are needed to verify exposure suggested by the models and limited monitoring data.

- The model estimate for average concentrations of azinphos-methyl in ground water was 0.44 ppb, and for surface water 7.2 ppb (excluding the 13.4 ppb estimate resulting from the potentially unrestricted number of applications possible to cotton). The lowest DWLOC for chronic exposure is 7 ppb (for non-nursing infants, <1 year old).

- Comments received did not significantly change the preliminary risk assessment for acute or chronic drinking water dietary risk.

Residential Risk

There are no residential uses.

Aggregate Risk

Aggregate risk looked at the combined risk from exposure through food and drinking water only. Generally, all risks from these exposures must be less than 100% of the acute and chronic RfDs.

For azinphos-methyl, the aggregate risk assessment does not include residential exposure, because there are no residential uses. Also, secondary exposures, such as spray drift are not included in the assessment. However, the Agency is currently developing a method to address secondary exposure.

- The acute aggregate risk was not calculated, because exposure to azinphos methyl from food sources alone exceeds the level of concern for acute dietary risk. Any additional exposure through drinking water would lead to risk estimates that further exceed the level of concern.

- Aggregate chronic risk (food and water) are not a concern, subject to additional monitoring data to verify exposure suggested by modeling and limited monitoring data, and based on six applications per year to cotton rather than 17. Note that registrants have agreed to limit applications to cotton to four per season.

Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and re-entering a treated site. Worker risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the No Observed Effect Level (NOAEL) taken from animal studies. Generally, MOEs that are greater than 100 do not exceed the Agency's risk concern. For workers entering a treated site, Restricted Entry Intervals (REIs) are calculated to determine the minimum length of time required before workers or others are allowed to enter.

Occupational risk estimates associated with application, mixing, loading and reentry activities exceed the level of concern for most exposure scenarios. The post-application risks to reentry workers greatly exceed the level of concern based on current REIs and application rates, even after the inclusion of better data from several recently submitted and reviewed dislodgeable foliar residue studies. Documented incident data on reported cases of azinphos-methyl exposure from reentering treated fields support occupational exposure and risk estimates. To achieve MOEs that are not a concern for post-application workers, most REIs would need to be significantly increased in length. Such increases may affect the efficacious use of azinphos-methyl

on many crops.

- For the short-term dermal endpoint, a NOAEL of 0.56 mg/kg/day based on red blood cell cholinesterase inhibition, was used. It was taken directly from a dermal absorption/toxicity study in rats; therefore, no dermal absorption factor was needed.

- For the intermediate-term dermal endpoint, an equivalent dermal dose of 0.36 mg/kg/day was derived by using the NOAEL from a one year oral toxicity study in dogs (0.149 mg/kg/day) and applying a dermal absorption factor (0.42) from a dermal absorption/toxicity study in rats. The endpoint was selected based on findings of significant decreases in red blood cell cholinesterase activity.

- For the inhalation endpoint, a NOAEL of 0.0012 mg/L was selected from a 90-day rat inhalation study based on inhibition of plasma and red blood cell cholinesterase.

- Comments received did not significantly change the preliminary occupational risk assessment.

Mixer/Loader/Applicator Exposure/Risk

- No chemical specific exposure data were available for the exposure assessments for mixer/loader/applicators. Short-term and intermediate-term dermal and inhalation exposure assessments were made using the Pesticide Handlers Exposure Database (PHED) Version 1.1 surrogate data.

- The representative treatment scenarios considered for mixers, loaders, and applicators and the associated application rates used are listed below:

Mixer/Loader

(1a) Mixing/loading liquids for aerial/chemigation application (cotton treated with 0.13-0.75 lb ai/A and tomatoes treated with 0.375-1.5 lb ai/A, 350 acres treated in each case);

(1b) Mixing/loading liquids for groundboom application (potatoes treated with 0.375-0.75 lb ai/A over 80 acres, and tomatoes treated with 0.375-1.5 lb ai/A over 50 acres);

(1c) Mixing/loading liquids for airblast sprayer application (pecans treated with 1.5 -2 lb ai/A, citrus treated with 1.25-2 lb ai/A, grapes treated with 0.75-1 lb ai/A, apples treated with 0.5-1 lb ai/A, and stone fruits treated with 0.875-2 lb ai/A, 20 acres treated for all scenarios);

(2a) Mixing/loading wettable powders for aerial application/chemigation irrigation (alfalfa treated with 0.25-0.5 lb ai/A, tomatoes treated with 0.375-1.5 lb ai/A, over 350 acres);

(2b) Mixing/loading wettable powders for groundboom application (potatoes treated with 0.375-0.75 lb ai/A over 80 acres, and tomatoes treated with 0.375-1.5 lb ai/A over 50 acres);

(2c) Mixing/loading wettable powders for airblast sprayer application (almonds treated with 1.5-2 lb ai/A, citrus treated with 1.25-2 lb ai/A, grapes treated with 0.7-1 lb ai/A, apples treated with 1-1.5 lb ai/A, and stone fruits treated with 0.875-2 lb ai/A, 20 acres treated for each scenario);

Applicator

(3) Applying sprays with fixed-wing aircraft (cotton treated with 0.13-0.75 lb ai/A and tomatoes treated with 0.375-1.5 lb ai/A, both scenarios over 350 acres);

(4) Applying sprays with helicopter (cotton and tomatoes with the same treatment scenario as in (3) above);

(5) Applying sprays using a groundboom sprayer (potatoes treated with 0.375-0.75 lb ai/A over 80 acres, and tomatoes treated with 0.375-1.5 lb ai/A over 50 acres);

(6) Applying sprays using an airblast sprayer (same treatment scenario as in (2c) above);

Mixer/Loader/Applicator

(7) Mixing/loading/applying sprays using a low pressure hand wand, spot treatment (ornamentals treated with 0.01-0.04 lb ai/gal. at 40 gallons);

(8) Mixing/loading/applying sprays using a high pressure hand wand, greenhouse (ornamentals treated with 0.01-0.04 lb ai/gal. At 1000 gallons).

- The PPE/Engineering controls assumed for each scenario are listed below:

(1) Closed mixing system, single layer of clothing, chemical resistant gloves.
(2) Water soluble packets, no gloves.
(3, 4) Enclosed cockpit, single layer of clothing, no gloves.
(5) Enclosed cab, single layer of clothing, no gloves.
(6) Enclosed cab, single layer of clothing, chemical resistant gloves.
(7, 8) Double layer of clothing, chemical resistant gloves.

The combined dermal and inhalation risks were calculated based on the maximum PPE and/or engineering controls described above. In all cases, most of the risk results from dermal exposure. All scenarios are of concern. Note that the registrants have voluntarily agreed to mitigation measures consisting of label changes requiring the following: 1) Full PPE or enclosed cabs for air blast applications; 2) All products to be in closed mixer/loader systems; 3) Prohibit the

use of human flaggers; 3) Prohibit the use of backpack sprayers; and 4) Delete greenhouse uses. These label changes have been submitted and approved by the Agency. For the crops not covered above, PPE requirements for applying or mixing/loading call for coveralls over long-sleeved shirt and long-legged pants, chemical resistant gloves, chemical resistant footwear with socks, and protective eyewear; plus chemical resistant apron when mixing/loading.

TABLE 2

Combined Dermal and Inhalation Risks Estimates (MOEs) for Occupational Scenarios with Engineering Controls. [MOEs greater than 100 are generally not a concern.]		
Exposure scenario	Short-term Risk Estimates (MOEs)	Intermediate-term Risk Estimates (MOEs)
1(a)	8-85	5-57
1(b)	55-69	35-45
1(c)	111-221	72-139
2(a)	3-11	2-7
2(b)	27	18
2(c)	55-91	35-60
3	15-27	9-18
4	35-70	23-45
5	80-90	51-59
6	60-108	39-70
7	7	5
8	<1	<1

- Although not included in the above scenarios, it is likely that in many cases the same person may mix, load and apply the pesticide for groundboom or airblast applications. In such cases (e.g., scenarios 1(b) or 2(b) combined with scenario 5; or scenario 1(c) combined with scenario 6) the risk estimates would be higher.

- Some additional mitigation may be achieved by reducing maximum application rates for several crops.

Post-Application Exposure/Risk

Risk estimates for reentry workers for all uses of azinphos-methyl (except its use in the WP50 formulation on tomatoes at 1.5 lbs ai/acre) pose serious risk concerns based on current application rates and REIs. Most REIs are currently two days. However, the registrants have

voluntarily agreed to mitigation measures consisting of label changes for all pome fruits, stone fruits, tree nut crops, citrus fruits and grapes requiring the following changes: 1) 14-day REI for apples, crabapples, pears, peaches, nectarines, and tree nut crops; 2) 21-day REI for grapes; 3) 30-day REI for citrus; and 4) 14-day PHI for all pome and stone fruits. These label changes have been approved to the Agency. However, even with these increased REIs serious risk concerns remain.

- Chemical-specific studies are available for estimating post-application worker exposure. In the preliminary assessment, none of the dislodgeable foliar residue (DFR) studies met all of the requirements to qualify as totally acceptable. However, the Agency used the most reliable data to perform the post-application exposure assessments. These data, when viewed in the context of other data available in the literature and the data conducted by the CDPR, were deemed adequate to estimate reentry exposure. The data from the various studies are consistent and reveal the slow dissipation rate for which azinphos-methyl is known. In response to the agricultural reentry data call-in and to the preliminary risk assessment, new DFR studies were submitted for apples and cotton. These studies were performed in more strict compliance with the Agency's requirements and can be considered more reliable. However, when compared to the results from the older studies, the recent studies present a corroborating picture of post-application risk, and did not significantly affect the risk estimates. Including old and new studies, DFR study data were available for tomatoes, potatoes, apples, grapes, cotton and citrus.

- Default transfer coefficients were used in all cases except orchard and citrus crops. Transfer coefficients show how readily residues transfer from foliage to workers who contact treated foliage. Transfer coefficients developed by the CDPR, based on measured values, were used for orchard and citrus crops.

- The available DFR data, how they are used, and the resulting risk estimates for each crop are presented in the table below. MOE estimates >100 are generally not a concern. A detailed analysis of these estimates can be found in the revised HED Science Chapter.

TABLE 3

Summary of Post-Application Exposure and Risk Estimates

Crop[a]	Form.	Rate (lb a.i/A)	No. of Applic.	Applic. Interval (days)	MOE	Current Max. Applic. Rate (lb ai/A)	Current REI
Tomatoes	2S	1.5	4	8-10	>100 day 8	1.5	2
	50WP	1.5	4	8-10	>100 day 1	1.5	2
Potatoes	2S	1.5	3	14	>100 day 13	0.75	2
	2S	0.75	3	14	>100 day 8	0.75	2
	50WP	1.5	3	14	>100 day 28	0.75	2
	50WP	0.75	3	14	>100 day 20	0.75	2
	50WP	0.5	3	14	>100 day 15	0.75	2
Apples[b]	50WP	1.0	4	21-26	8.0 day 2 (propper) 0.4 day 2 (thinner) 0.9 day 21 (harvester)	1.5	14
Citrus		2.0			2.0 day 7 3.7 day 30 (harvester)	3.0	30
Grapes		0.25			0.4 day 21 (various tasks)	1.0	21
Caneberries / Blueberries		0.25			2.2 day 7 (various tasks)	2.0	2
Cotton	2L	0.25	3		>100 day 15[c] (TX) >100 day 7 (MS) >100 day 0 (GA)	1.0	2

[a] The risk estimates for these representative crops will be applied to other crops as follows: 1) For potatoes: also applies to broccoli, Brussels sprout, cabbage, cauliflower, celery, cucumbers, eggplants, onions, and parsley; 2) For apples: also applies to almonds, apricots, cherries, crabapples, filberts, peaches, pears, pecans, pistachios, plums, quinces, and walnuts; 3) For citrus crops: also applies to kiwi fruits and pomegranates; and 4) For grapes, caneberries & blueberries: also applies to snap beans, blackberries, boysenberries, loganberries, raspberries, cranberries, gooseberries, melons, blackeyed peas, peppers, soybeans, and strawberries.

[b] The reported study was conducted in Washington State. Under similar study conditions, similar results were obtained in an Oregon study, while slightly higher MOEs were observed in CA and NY for proppers (MOEs 19 & 28) and harvesters in NY (MOEs 2.3 to 9.3). Note that post-application risk is considered to be negligible for mechanical harvesting of crops. This may apply to almonds and other tree nut crops. However, activities ancillary to any mechanical harvesting (this may include the use of mechanical blowers to move fallen nuts into wind rows) can present potentially high post-application exposures.

[c] The data from TX are much higher quality than those from MS & GA. When the application rate is prorated to 0.5 and 0.75 lb ai/A the MOEs for GA are >100 on day 5 and day 11, respectively.

Ecological Risk Assessment

The EFED Science Chapter was completed on November 17, 1998. This preliminary ecological risk assessment for azinphos-methyl was placed in the Public Docket on January 15, 1999 for a 60-day public comment period. The public comment period closed on March 16, 1999. The ecological risk assessment and risk management proposal is subject to refinement based on a review of the comments received. The refined ecological risk assessment and the Agency's response to comments on the preliminary ecological risk assessment should be completed within the next few weeks. The preliminary ecological risk assessment states with a high degree of certainty that azinphos-methyl poses a very high risk to aquatic organisms and could be among the highest of the organophosphates because of a high potential for exposure due to surface water runoff and spray drift; and also poses a high chronic risk to terrestrial organisms. Additionally, the assessment finds that of the organophosphates applied foliarly, azinphos-methyl is one of the most persistent in the environment.

Summary of Public Comments

Twenty three comments were received during the open public comment period. Of these, eight comments specific to azinphos-methyl were received from the registrant (Bayer Corporation), Michigan Processing Apple Growers, Cherry Marketing Institute, Inc., Michigan Farm Bureau, Almond Hullers and Processors Association, Consumers Union, National Resources Defense Council, and Northwest Horticultural Council. An additional ten comments were received after the public comment period closed. Of these, eight comments specific to azinphos-methyl were received. Revisions and refinements to the risk assessment were based primarily on a review of additional data submitted by the registrant, and data available from USDA (PDP data) and FDA. Comments concerning use patterns and benefits are being considered by the Biological and Economic Analysis Division (BEAD).

ATTACHMENT I. Explanation of Data Used in the Monte Carlo Analysis

BLENDED COMMODITIES

The following items are considered blended commodities in this analysis. **Bolded** commodities are those which are not generally considered to be blended under current HED policy. However, they have been considered (partially) blended for this analysis only. In any case, it is not expected that these commodities will be significant contributors to risk.

almonds
apple juice concentrate
blackberry juice
boysenberries
celery juice
cherries
cherries, juice
cranberry juice
dewberries
grape juice
grapefruit juice
lemon juice
lime juice
loganberries
orange juice concentrate
Pear nectar
plum/prune juice
Raspberries
Strawberry juice
Tangerine juice, concentrate
tomato catsup
tomato puree
walnut
apple juice, cider
blackberries
blueberries
cantaloupe nectar
celery seed
cherries, dried
cranberries
cranberry juice concentrate
filberts
grape juice concentrate
grapefruit juice, concentrate
lemon juice concentrate
lime juice concentrate
orange juice
peach juice
pecan
potatoes, dry
strawberries
tangerine juice
tomato juice
tomato paste
walnut oil
watermelon juice

In the Monte Carlo assessment, blended commodities are handled in several ways depending on the type of data available and whether the commodity has been processed.

Unprocessed

8) Where no monitoring data are available, the analysis uses the average of the field trial residue data incorporating % crop treated and ½ the Limit of Detection (LOD) for non-detects.

4) For small sized commodities (the ones in bold above) some degree of blending is assumed; therefore, where monitoring data were available, the analysis uses the full distribution of monitoring data without adjustment for single servings, uses percent crop treated, and uses ½ the LOD for all non-detects.

Processed

9) Where no monitoring data are available, the analysis uses the average of the field trial residue data incorporating % crop treated, uses ½ the LOD for non-detects, and corrects for residue reduction/concentration during processing.

5) Where monitoring data are available for the related unprocessed commodity (e.g. cherries for cherry juice), the analysis uses the processing factor for the processed commodity multiplied by the average residue for the unprocessed commodity (which incorporates ½ the LOD and % crop treated).

6) Where monitoring data are available for the processed commodity itself (e.g. apple juice PDP data for apple juice), then the analysis uses the entire distribution of the monitoring data with no further adjustment for % crop treated.

Single Serving Commodities

Where monitoring data are available, the commodities were handled in four ways depending on the type, number and amount of detects.

1) Where greater than 30 detects were found, the data were adjusted to reflect single servings using ½ the LOD and % crop treated. For azinphos-methyl, peach data were adjusted to reflect single servings and these data were then used for similar crops.

2) If less than 30 detects were found, the monitoring data were used directly including ½ the LOD and % crop treated.

3) If the monitoring data showed numerous years in which no detectable residues were found, then ½ the LOD was used as a point estimate.

7) Where no monitoring data were available, field trial data were used. The entire distribution of data from the field trials was used incorporating % crop treated and ½ the LOD for non-detects. Note that regardless of whether ½ the limit of detection or zeros are used for non-detects in the analysis, the results are not significantly affected.

10) Where single serving PDP monitoring data (for pears) were available the data were used directly, including ½ the LOD and % crop treated. For azinphos-methyl pear data were then used for similar crops.

The chart that follows shows what data were used for each specific commodity. The "Analysis Scenario" column gives the number for the general scenario described above which was used for that crop.

Crop by Crop Description of Specific Data Used in Revised Analysis.

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Alfalfa Sprouts	Tolerance of 2 ppm and 1% CT.	N/A	<0.5% [5]	
Almonds	Point estimate which = mean FT[2] data X 39% CT and assumed all almonds are at this level. 0.009 X 0.39 = 0.0035 [Field trials used 2 lb ai/A, 3 applications, PHI of 28 days].	8	39%	
Apples	Single Serving PDP[3] pear data incorporating 88% CT used for apples except cooked where a point estimate was used =0.037.	10	88%	
Apples, Dried	Single Serving PDP[3] pear data incorporating 88% CT and a concentration factor.	10	88%	
Apple Juice, Concentrate	Full distribution of PDP apple juice data and a concentration factor.	6	N/A	
Apple Juice, Cider	Full distribution of PDP apple juice data.	6	N/A	
Beans, Succulent	Composite PDP green bean data directly incorporating 1% CT.	2	<0.5%[5]	Few PDP residues (10) detected in three years of PDP data. Total of 1810 samples.
Blackberries	Composite FDA raspberry data directly incorporating 14% CT.	4	14%[6]	
Blackberry Juice	Point estimate using FDA raspberry data incorporating ½ LOD[4] and 14% CT = 0.002. Point estimate multiplied by processing factor.	5	14%[6]	
Blueberries	Composite FDA blueberry data directly incorporating 51% CT.	4	51%	
Boysenberries	Composite FDA raspberry data directly incorporating 14% CT.	4	14%[6]	

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Broccoli	Composite PDP spinach data directly and 1% CT.	2	1%	Few PDP residues (4) detected in three years of PDP data. Total of 1806 samples.
Brussels Sprouts	Composite PDP spinach data directly and 2% CT.	2	2%	Few PDP residues (4) detected in three years of PDP data. Total of 1806 samples.
Cabbage, Green and Red	Cabbage FT data and 13% CT.	7	13%	
Cabbage Savoy	Cabbage FT data and 13% CT.	7	13%	
Cantaloupe Nectar	No detectable residue. Used point estimate equal to ½ LOD[4] = 0.0015	3	N/A	Not detected in four years of FDA monitoring (1994-97).
Cantaloupe Pulp	No detectable residue found. ½ LOD used incorporating 5% CT.	3	5%	Not detected in four years of FDA monitoring (1994-97).
Casaba	No detectable residue found. ½ LOD used incorporating 2% CT.	3	2%	Not detected in four years of FDA monitoring (1994-97).
Cauliflower	Composite PDP spinach data directly and 2% CT.	2	2%	Few PDP residues (4) detected in three years of PDP data. Total of 1806 samples.
Celery	Composite PDP spinach data directly and 13% CT.	2	13%	Few PDP residues (4) detected in three years of PDP data. Total of 1806 samples.
Celery Juice	Point estimate using PDP spinach data incorporating ½ LOD and 13% CT = 0.0030. Point estimate multiplied by processing factor.	5	13%	

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Celery Seed	Point estimate using PDP spinach data incorporating ½ LOD and 13% CT = 0.0030. Point estimate multiplied by processing factor.	5	13%	
Cherries	Composite FDA cherries data directly incorporating 58% CT for sweet cherries and 80% CT for tart cherries.	8	58/80%[7]	
Cherries, Dried	Composite FDA cherries data directly incorporating 58% CT for sweet cherries and 80% CT for tart cherries and an concentration factor.	Similar to 8	58/80%[7]	
Cherry Juice	Point estimate of FDA cherry data incorporating ½ LOD and 58% CT = 0.002. Point estimate multiplied by processing factor.	Similar to 8	58%	
Citrus Citron	Composite PDP orange data directly and 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Cottonseed	Tolerance of 0.5 ppm and 11% CT.	N/A	11%	
Crabapples	Single Serving PDP Pear incorporating 1% CT.	10	<0.5%[5]	
Cranberries	Point estimate of cranberries mean FT data multiplied by 69% CT. 0.03X 0.69 = 0.021. [Field trials used 1.0 lb ai/A, 3 applications, PHI of 21 days].	8	69%	
Cranberry Juice	Point estimate of mean FT data multiplied by 69% CT. 0.03 X 0.69 = 0.021. Point estimate multiplied by processing factor. [Field trials used 1.0 lb ai/A, 3 applications, PHI of 21 days].	9	69%	

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Cranberries Juice Concentrate	Point estimate of mean FT data multiplied by 69% CT. 0.03 X 0.69 = 0.021. Point estimate multiplied by processing factor. [Field trials used 1.0 lb ai/A, 3 applications, PHI of 21 days].	9	69%	
Crenshaw	No detectable residue found. ½ LOD used incorporating 2% CT.	3	2%	Not detected in four years of FDA monitoring (1994-97).
Cucumbers	No detectable residue found. ½ LOD used incorporating 3% CT.	3	3%	Not detected in four years of FDA monitoring (1994-97).
Dewberries	Composite FDA raspberry data directly and incorporating 14% CT.	4	14%[6]	
Filberts	Point estimate of mean of pecan FT data X 39% CT = 0.0156 [Field trials used 2.0 lb ai/A, 3 applications, PHI of 45 days].	8	39%	
Grapes	Composite PDP grape data directly and incorporating 2% CT.	2	2%	Low PDP residues (<0.05 ppm) detected in two years of PDP data. Total of 1215 samples.
Grape Juice	Point estimate of mean of PDP grape data X 2% CT = 0.0006. Point estimate multiplied by a processing factor.	5	2%	
Grape Juice Concentrate	Point estimate of mean of PDP grape data X 2% CT = 0.0006. Point estimate multiplied by a processing factor.	5	2%	
Grapes-Raisins	Composite PDP grape data directly and incorporated 2% CT and concentration factor.	Similar to 2	2%	Low PDP residue (<0.05 ppm) detected in two years of PDP data. Total of 1215.

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Grape Leaves	Composite PDP grape data directly and incorporated 2% CT.	Similar to 2	2%	Low PDP residues (<0.05 ppm) detected in two years of PDP data. Total of 1215 samples.
Grapefruit Juice	Full distribution of PDP orange juice data.	6	N/A	
Grapefruit Juice Concentrate	Full distribution of PDP orange juice data and a processing factor.	Similar to 6	N/A	
Grapefruit Peel	Composite PDP orange data directly and incorporated 17% CT.	2	17%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Grapefruit Peeled Fruit	Composite PDP orange data directly and incorporated 17% CT.	2	17%	Few PDP residues (3) detected in three years of PDP data. Total Samples = 1209.
Honeydew Melons	No detectable residue found. ½ LOD used incorporating 2% CT.	3	2%	Not detected in four years of FDA monitoring (1994-97).
Kumquats	Composite PDP orange data directly and 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209 .
Leeks	Green onion FT data and 2% CT. [Field trials used 0.75 lb ai/A, 3 applications, PHI of 14 days]	7	2%	
Lemon Juice	Full distribution of PDP orange juice data.	6	N/A	
Lemon Juice Concentrate	Full distribution of PDP orange juice data and processing factor.	Similar to 6	N/A	
Lemon Peel	Composite PDP orange data directly and 1% CT.	Similar to 2	<0.5%[5]	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Lemon Peeled Fruit	Composite PDP orange data directly and 1% CT.	Similar to 2	<0.5%[5]	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Lime Juice	Full distribution of PDP orange juice data.	6	N/A	
Lime Juice Concentrate	Full distribution of PDP orange juice data and a concentration factor.	Similar to 6	N/A	
Lime Peel	Composite PDP orange data directly and incorporating 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Limes Peeled Fruit	Composite PDP orange data directly and incorporating 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Loganberries	Composite FDA raspberry data directly and incorporating 14% CT.	4	14%[6]	
Nectarines	Composite PDP peach data adjusted for single servings incorporating 6% CT.	1	6%	689 detects from three years of PDP data (1995-1997). Total Sample = 1393.
Onions, Green	Green onion FT data and incorporating 2% CT. [Field trials used 0.75 lb ai/A, 3 applications, PHI of 14 days].	7	2%	
Onions, Dehydrated or Dried	Bulb onion FT data and incorporated 2% CT and processing factor. [Field trials used 0.75 lb ai/A, 3 applications, PHI of 21 days].	7	2%	
Onions, Dry Bulb	Bulb onion FT data and incorporated 2% CT.	7	2%	

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Orange Juice	Full distribution of PDP orange juice data.	6	N/A	Used PDP orange juice data as blended although not generally considered to be blended. Rationale: comparable residues in orange and orange juice.
Orange Juice Concentrate	Full distribution of PDP orange juice data and a concentration factor.	Similar to 6	N/A	Used PDP orange juice data as blended although not generally considered to be blended. Rationale: comparable residues in orange and orange juice.
Orange Peel	Composite PDP orange data directly incorporating 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Orange Peeled Fruit	Composite PDP orange data directly incorporating 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Peaches	Composite PDP peach data adjusted for single servings and incorporated 30% CT except point estimate equal to 0.02 ppm used for canned and boiled food forms.	1	30%	689 detects from three years of PDP data (1995-1997). Total samples = 1393.
Peaches, Dried	Composite PDP peach data adjusted for single servings incorporating 30% CT and processing factor.	1	30%	689 detects from three years of PDP data (1995-1997). Total samples = 1393.
Peaches, Juice	Point estimate using PDP peach data incorporating ½ LOD and 30% CT = 0.0157. Point estimate multiplied by processing factor.	5	30%	

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Pears	Single Serving PDP pear data and incorporating 91% CT except point estimate equal to 0.059 ppm used for canned and boiled food forms.	10	91%	
Pears, Dried	Single Serving PDP pear data incorporating 91% CT and processing factor.	10	91%	
Pear Nectar	Full distribution of apple juice PDP data.	Similar to 6	N/A	
Pecan	Point estimate which = mean FT data X 3% CT= 0.0012 [Field trials used 2.0 lb ai/A, 3 applications, PHI of 45 days].	8	3%	
Persian Melon	No detectable residue found. ½ LOD used incorporating 2% CT.	3	2%	Not detected in four years of FDA monitoring (1994-97).
Pistachios	Point estimate of mean of pecan FT data X 48% CT = 0.0172 [Field trials used 2.0 lb ai/A, 3 applications, PHI of 45 days].	8	48%	
Plum	Composite PDP peach data adjusted for single servings and incorporated 12% CT except point estimate equal to 0.02 ppm used for canned food forms.	1	12%	689 detects from three years of PDP data (1995-1997). Total Samples = 1393.
Plum/Prunes, Dried	Composite PDP peach data adjusted for single servings, incorporating 12% CT and processing factor.	1	12%	689 detects from three years of PDP data (1995-1997). Total Samples = 1393.
Plum/Prune Juice	Point estimate using PDP peach data and incorporating 12%CT = 0.0104. Point estimate multiplied by processing factor.	5	12%	

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Potatoes (White), Dry	No detectable residues found. ½ LOD = 0.011 ppm used	3	N/A	Not detected in two years of PDP monitoring (1995-96).
Potatoes (White) Unspecified	No detectable residue found. ½ LOD used incorporating 10% CT.	3	10%	Not detected in two years of PDP Monitoring (1995-96).
Potatoes (White), Whole	No detectable residue found. ½ LOD used incorporating 10% CT.	3	10%	Not detected in two years of PDP Monitoring (1995-96).
Quince	Single Serving PDP pear data and incorporating 75% CT.	10	75%	
Raspberries	Composite FDA raspberry data directly and incorporating 14% CT.	4	14%	
Shallots	Bulb onion FT data and incorporated 2% CT.	7	2%	
Strawberries	Composite FDA raspberry data directly and incorporating 12% CT.	4	12%	
Strawberry Juice	Point estimate using FDA strawberry data incorporating ½ LOD and 12% CT = 0.0025.	5	12%	
Tangelos	Composite PDP orange data directly and 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples =1209.
Tangerines	Composite PDP orange data directly and 3% CT.	2	3%	Few PDP residues (3) detected in three years of PDP data. Total samples = 1209.
Tangerine Juice	Full distribution of PDP orange juice data.	6	N/A	Used PDP orange juice data as blended although not generally considered to be blended. Rationale: comparable residues in orange and orange juice.

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Tangerine Juice Concentrate	Full distribution of PDP orange juice data and a concentration factor.	Similar to 6	N/A	Used PDP orange juice data as blended although not generally considered to be blended. Rationale: comparable residues in orange and orange juice.
Tomato Juice	Point estimate using PDP tomato data incorporating ½ LOD and 11% CT = 0.0031. Point estimate multiplied by processing factor.	5	11%	
Tomato Catsup	Point estimate using PDP tomato data incorporating ½ LOD and 11% CT = 0.0031. Point estimate multiplied by processing factor.	5	11%	
Tomato Paste	Point estimate using PDP tomato data incorporating ½ LOD and 11% CT = 0.0031. Point estimate multiplied by processing factor.	5	11%	
Tomato Puree	Point estimate using PDP tomato data incorporating ½ LOD and 11% CT = 0.0031. Point estimate multiplied by processing factor.	5	11%	
Tomato, Whole	Composite PDP tomato data and incorporated 10% CT for unprocessed and 11% CT for processed tomatoes.	2	10%/11 %	Low PDP residues (<0.1) detected in three years of PDP data. Total of 879 samples.
Tomato, Dried	Composite PDP tomato data directly incorporating 10% CT and concentration factor.	2	10%	Low PDP residues (<0.1) detected in three years of PDP data. Total of 879 samples.
Walnut Oil	Point estimate using mean FT X 30% CT = 0.029. Point estimate multiplied by processing factor. [Field trials used 2.0 lb ai/A, 3 applications, PHI of 21 days].	9	30%	

Crop	Residue Data Used	Analysis Scenario	%Crop Treated (CT[1])	Comments on data Selected
Walnuts	Point estimate using mean FT X 30% CT = 0.029. [Field trials used 2.0 lb ai/A, 3 applications, PHI of 21 days].	8	30%	
Watermelon Juice	No detectable residues found. ½ LOD = 0.0015 used	2	N/A	Not detected in four years of FDA monitoring (1994-97).
Watermelon	No detectable residue found. ½ LOD used incorporating 2% CT.	2	2%	Not detected in four years of FDA monitoring (1994-97).
Wintermelon	No detectable residue found. ½ LOD used incorporating 2% CT.	2	2%	Not detected in four years of FDA monitoring (1994-97).

[1] %CT = Percent Crop Treated. Biological and Economic Division (BEAD) estimated percent crop treated used for all commodities except kumquats, crabapples and quinces, which were registrant supplied percent crop treated values.
[2] FT = Field Trial
[3] PDP = Pesticide Data Program - This is a USDA pesticide residue monitoring program.
[4] LOD = Level of Detection
[5] When BEAD reports <0.5% crop treated (CT), 1% CT was used.
[6] Used % crop treated for raspberry
[7] 58% CT used for sweet cherries; 80% CT used for tart cherries.